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EXAMINER

CHONG, YONG SOO

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/691,896
Filing Date: October 19, 2000
Appellant(s): THENO, MARK H.

MAILED
FEB 09 2007
GROUP 1600

Mark H. Theno
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/20/2006 appealing from the Office action mailed 3/20/2006.

(1) *Real Party in Interest*

A statement identifying by name the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) *Status of Claims*

The statement of the status of claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) *Summary of Claimed Subject Matter*

The summary of the claimed subject matter contained in the brief is correct.

(6) *Grounds of Rejection to be Reviewed on Appeal*

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) *Claims Appendix*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) *Evidence Relied Upon*

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

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Cartmell et al. (US Patent 5,501,661)

Fischel-Ghodsian et al. (US Patent 5,455,043)

Wick et al. (US Patent 6,010,715)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-8, 10-12, 17-20, 23-27, 29-30, 40, 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. (US Patent 5,501,661) in view of Fischel-Ghodsian et al. (US Patent 5,455,043).

Cartmell et al. teach a wound dressing product containing a porous layer. The wound dressing product comprises an optional release liner, an optional removable tab,

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and a wound dressing. The wound dressing comprises a thin-film layer, an adhesive layer, a porous backing layer, an optional support layer and a hydrogel material. The thin-film layer has a first side and an opposing second side and forms the outer surface of the dressing product. The adhesive layer is positioned on the second side of the thin-film layer. The backing layer is constructed of a porous material comprising a polyolefin foam (col. 2, lines 19-32). The porous backing layer has a first side and an opposing second side, and is adhered to the second side of the thin-film layer by the adhesive layer. The optional support layer is made from a material such as woven and non-woven fabrics. The hydrogel material may be secured to the second side of the support layer. The permeable fabric of the support layer allows the hydrogel material to pass through to the first side of the support layer. The optional release liner overlies the hydrogel material and is secured to the perimeter portion of the second side of thin-film layer by means of the adhesive layer. The optional removable tab is interposed between the thin-film layer and the release liner. The porous layer obviates the need for a second adhesive layer, and is moisture and vapor permeable (col. 2, lines 36-58). Cartmell et al. clearly teach that the invention is designed to permeate vapor "which permits the transpiration of moisture through the wound dressing." Thus, the reference clearly teaches that a skilled artisan would have expected that the invention be used to transport vapors.

While the reference does not explicitly state that vapor emitting materials are stored within the foams, examiner respectfully points out that it is implicit in the

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teachings of Cartmell et al., as the foam layer is the layer through which vapor-permeable substances are transferred from the wound to the environment.

The reference teaches that the structure of the patch as claimed is well known in the art, except that the reference is silent as to the cellular structure of the foam. The reference fails to teach that a vapor emitting material is stored in the patch "prior to use."

Fischel-Ghodsian et al. teach patches comprised of foams, such as polyolefin, polypropylene, and polyethylene foams. The reference teaches that varying the porosity of the cellular structure of the foam is within the skill of the art (col. 5, lines 14-25). The reference teaches that the active ingredients in the vapor emitting compounds can be perfumes, various fragrances, air fresheners, insecticides, and insect repellents. The active agent can also be therapeutic agents such as vapor emitting compounds, and those which are typically delivered by aerosol or spray inhalation. These therapeutic agents include antihistamines, bronchodilators, decongestants, anti-tussives, mucolytics, steroids, anti-virals, hormones, and peptides (col. 4, lines 1-9). These active ingredients are incorporated in the reservoir layer of the patch (col. 6, line 56 to col. 7, line 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the polyolefin foams of Cartmell et al. with suitable polymers that possess a diffusion rate limiting membrane layer as taught by Fischel-Ghodsian et al. because using such polymers (polyolefin foams) will enable one to control the amount and rate of emission of the active agent due to the porosity of the cell sizes of the membrane. Incorporation of vapor emitting compounds in the foams of

Cartmell et al. is viewed as an obvious variation of the prior art in view of Fischel-Ghodsian et al. because the skilled artisan would have been motivated to successfully produce a therapeutic medication.

Claims 13, 14, 21, 22, 28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. in view of Fischel-Ghodsian et al. as applied to claims 1, 3-8, 10-12, 17-20, 23-27, 29-30, 40, 42-44 as above, and further in view of Wick et al. (US Patent 6,010,715).

Cartmell et al. and Fischel-Ghodsian et al. are applied as discussed above. The references lack a teaching of the release layer made from polyolefin, polyamide, cellulosic, or polyethylene terephthalate.

Wick et al. teach transdermal patches. The backing layer is taught as being made from cellulose acetate, ethyl cellulose, polyethylene terephthalate and other materials. These compounds are taught as being made of a material that is substantially impermeable to the layer or layers with which it can be in contact. The patches are taught as being kept sealed in an air-tight pouch prior to use (col. 14, lines 34-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the release liner material of Cartmell et al. with cellulose acetate, ethyl cellulose, or polyethylene terephthalate, as taught by Wick et al. because of the expectation of achieving a product that is impermeable to the hydrogel, thereby keeping the product intact.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the patches of the combined references as being kept

sealed in an air-tight pouch prior to use, and thereby having to remove the patch from the seal for use, as taught by Wick et al., because of the expectation of achieving a patch that is sterile.

(10) Response to Argument

Appellant's arguments have been fully considered but found not persuasive. Appellant assert that the Cartmell et al. reference does not teach a vapor emitting material. Appellant further asserts that the Fischel-Ghodsian et al. and Wick et al. references describe a device for releasing vapors absent a hydrogel. Appellant also argue that there is no motivation for substituting the foam of Cartmell et al. with the foam taught by Fischel-Ghodsian et al.

In response to Appellant's arguments against the references, one cannot show nonobviousness by attacking references individually where the rejections are based on the combination of references. See *In re Keller*, 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Firstly, the motivation to substitute the polyolefin foam of Cartmell et al. with the polyolefin foam taught by Fischel-Ghodsian et al. is because of the increased porosity of the cell sizes in the foam. The reference teaches that varying the porosity of the cellular structure of the foam is within the skill of the art (col. 5, lines 14-25). Hence, the modification of the invention described by Cartmell et al. by substituting the existing polyolefin foam with superior polyolefin foam described by Fischel-Ghodsian et al. is indeed the motivation. Although the motivation for adjusting porosity in the Cartmell et al. patent is not the same as the motivation of the instant claims, the two motivations do

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not have to coincide. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the polyolefin foams of Cartmell et al. with suitable polymers that possess a diffusion rate limiting membrane layer as taught by Fischel-Ghodsian et al. because using such polymers (polyolefin foams) will enable one to control the amount and rate of emission of the active agent due to the porosity of the cell sizes of the membrane. Examiner does not have to show that Cartmell et al. ever cared about increased porosity of cell sizes in the foam since the motivation comes from the Fischel-Ghodsian et al. reference.

In response to Appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Appellant argue that the "transpiration of moisture" functionality of Cartmell et al. teaches away from the device embodiments claimed which include "a vapor emitting material stored within the vapor emitting portion," and indicate that the storage of a vapor emitting material within the Cartmell et al. bandage is undesirable.

This is not persuasive because Appellant has misinterpreted the Cartmell et al. reference. Nowhere does it state that the storage of a vapor emitting material is

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undesirable in the compositions disclosed by Cartmell et al. Examiner was simply stating the fact that the compositions disclosed by Cartmell et al. are capable of storing a vapor emitting material since the composition is vapor permeable.

Appellant argues that there is no suggestion that the feature of a "vapor emitting material stored within the vapor emitting portion" would be useful or desirable.

The vapor emitting material contains active ingredients that are classified as drugs, pheromones, and perfumes. There is sufficient motivation to incorporate a vapor emitting material into a wound dressing. Various active ingredients that were disclosed include insecticides, insect repellants, antihistamines, steroids, and peptides. It would have been obvious to one of ordinary skill in the art to have incorporated these vapor emitting drugs into a wound dressing in order to assist in the healing of the injury or protection of the break in the skin. For example, insecticides can be added for the purpose of warding off disease and germ carrying insects from the open wound. Antihistamines and steroids can be used to inhibit any allergic reaction the wound would have to any foreign allergen. Peptides can be used for their antimicrobial activity in helping to protect the open wound from infection.

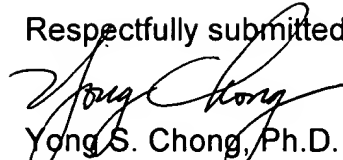
(11) *Related Proceeding(s) Appendix*

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,



Yong S. Chong, Ph.D.

Patent Examiner

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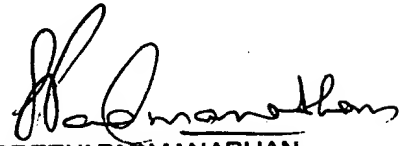
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January 31, 2007

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